Point-of-care testing for HIV: HIV counselling and testing

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Testing and counselling are key elements in the effort to control HIV. Data suggest that HIV-infected individuals who are aware of their status are more likely to adopt risk reduction behaviours than those who are not (1). With a diagnosis of HIV, consideration may be given to the initiation of antiretroviral treatment, which reduces viral load and infectivity (2). From a public health perspective, it is advisable to recommend testing to those at risk for HIV and to make testing easily accessible. A May 2001 *Epi Update* (3) from Health Canada indicated that up to one-third of prevalent HIV infections in Canada may not be diagnosed. Given the role that one's knowledge about his or her serostatus plays, it is important to examine any strategy that might improve testing uptake. One newer strategy is point-of-care testing (also known as rapid testing).

Standard HIV testing involves pretest counselling and HIV testing in an approved laboratory, with the person returning at a later date for the test result and post-test counselling (4). Point-of-care testing refers to counselling and screening completed while a person waits, with subsequent confirmatory testing as needed (4). Testing and reporting can be nominal, non-nominal or anonymous, with any one of these strategies applied to standard or point-of-care tests. Whatever the testing strategy, HIV testing and counselling must be confidential, with consent that is explicit, informed and voluntarily given (4-6).

Several laboratory methods are available to detect infection with HIV. HIV antibody tests can be viewed broadly as two types – screening and confirmatory. The most commonly used antibody screening tests are enzyme immunoassays (EIAs), also known as ELISAs. EIAs are used for both standard and rapid screening tests, and are able to detect antibodies to both HIV-1 and HIV-2. However, the EIAs used in the standard procedure are more complex than those used in the rapid screening tests and need to be performed in the laboratory setting.

As screening tests intended to maximize the detection of infected individuals, EIAs have a high sensitivity, in excess of 99%, and a specificity of 98.5% (7). Although false negatives can occur, they are rare and usually occur as the result of a patient being in the window period, when insufficient antibody has formed to be detected by the EIA. With the available tests, the window period has been reduced to 28 days on average and may be reduced even further with newer assays (8). A negative EIA (whether by standard or point-of-care test) is considered to exclude HIV infection, provided the person is not in the window period. In a low prevalence population, even with a highly specific test, most positive EIAs are false positives, and consequently, a confirmatory test is performed for every reactive EIA. Only a positive confirmatory test can be used to definitively diagnose HIV serologically (4). For standard testing, a reactive EIA is not usually reported unless the confirmatory test is positive. With point-of-care testing, however, the positive screen will be reported to the patient before the opportunity for confirmation. This is an important difference between standard and point-of-care testing.

The Western blot is the most commonly used confirmatory test. It has a sensitivity of 99.3% and a specificity of 91.6% (7). The lower specificity is contributed to by indeterminate results (7). It is very rare to have either a false positive or negative Western blot (9,10). However, laboratory and labelling errors do occur, and a Western blot may be negative during the window period. In addition, the HIV vaccine will produce a false positive result (8,9). The window period is one reason for an indeterminate Western blot; the test may be given when antibodies to all of the HIV antigens that characterize the positive test have not yet developed (8,11). However, the reason for many indeterminate Western blots is not known. Most individuals who remain repeatedly Western blot indeterminate in the absence of recent exposures should be considered HIV neg-

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TABLE 1
Performance characteristics of point-of-care HIV test kits

Rapid test (reference)	Setting	HIV prevalence	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Genie HIV-1/2 (19) (Sanofi Pasteur Diagnostics, France)	Hospital laboratory	5.4%	100	99.1	86.5	100
Fast-Check HIV-1/2 (25) (Biochem Immunosystems Inc, Canada)	Unknown	Unknown	100	99.96	N/A	N/A
Fast-Check HIV-1/2 (26)	Unknown	Unknown	99.9	99.92	N/A	N/A
SUDS (15) (Abbott Diagnostics, USA)	Emergency department	5.4%	100	98.89	75	100
Medmira (27) (Medmira Laboratories, Canada)	Hospital laboratory	Unknown	100	99.4	N/A	N/A
SUDS (18)	HIV testing clinic	2.4%	100	99.5	80.9	100
SUDS (18)	STD clinic	2.9%	100	99.5	88	100

NPV Negative predictive value; PPV Positive predictive value; STD Sexually transmitted disease

ative and counselled as such (9,11). Until that determination is made, however, counselling for an indeterminate Western blot should be the same as that for a newly identified HIV (9). The Western blot, also a complex test, is performed only in specialized laboratories. For some localities, this means that specimens have to be shipped to another city. The need to allow sufficient time for shipping and confirmatory tests primarily accounts for the time that it takes to receive HIV test results. This time factor also applies when a rapid screening test needs to be confirmed.

Both Canada and the United States have developed guidelines for HIV counselling and testing. The American guidelines have been updated to accommodate the changes brought about by rapid testing and to include guidelines on prevention counselling (9). With prevention counselling, the individual and the counsellor together focus on assessing the individual's HIV risk, and in two or more sessions, identify attainable goals to reduce the risk. One model of prevention counselling has been effective in reducing risk behaviours and new sexually transmitted diseases (12). Most often, and particularly in the physician office setting, the focus of counselling is informational rather than preventive (9,13). A Canadian study found that 17% of physicians testing patients for HIV provided counselling only to those who were positive, raising concerns about the quality of counselling (13). With standard testing, counselling occurs before and after testing. Pretest counselling includes a risk screening to evaluate the individual's likelihood of having HIV. Information that should be part of pretest counselling is thoroughly outlined in Canadian and American testing guidelines (5,9). Post-test counselling takes place when the individual returns for the test result. If the test is negative, risk reduction strategies are reinforced. If the person may be in the window period, plans for follow-up testing are made with a reminder to continue transmission prevention strategies. If the test is positive, the emphasis is on the benefits of early treatment and follow-up, psychosocial supports available, and the steps that can be taken to reduce transmission to others. The need for contact tracing needs to be addressed in a timely fashion.

With point-of-care testing, there will be a result at one visit: either a confirmed negative or a reactive screen. Pre- and post-test counselling take place during one visit rather than two. In addition to the elements of pretest counselling for standard testing, several points need to be made regarding point-of-care testing (4,9). The individual must know that a rapid test is being used, the charge for the kit (when the patient will be responsible for its cost) and the availability of a result during that visit. The individual needs to know that there is a possibility of a false positive as well as a true positive result. A positive or equivocal screen requires laboratory confirmatory testing, with a usual one- or two-week wait for the result. Post-test counselling for a negative point-of-care test is similar to that of the standard procedure. If the test is reactive, it must be emphasized that it is a screening, not a confirmatory, test. Depending on the individuals's risk for HIV and the prevalence of HIV in the setting specific to the individual, there may be some discussion of the meaning of the result – whether it is more likely to be a false or true positive (9). In this setting, a follow-up appointment is necessary to obtain the result of the confirmatory test, provide information about resources that can provide psychosocial support and discuss transmission prevention behaviours.

POINT-OF-CARE HIV TESTS: TEST CHARACTERISTICS, ADVANTAGES AND DISADVANTAGES

In Canada, point-of-care HIV test kits were licensed for sale to and use by health care professionals in March 2000. There are no systems in place to monitor the distribution of the kits. It is provincial and territorial legislation that defines health services and, therefore, defines who is legally permitted to administer these tests (6). Two rapid HIV test

kits are licensed in Canada: the Fast-Check HIV-1/2 from Biochem Immunosystems Inc (Canada) and Medmira Rapid HIV Test & Medmira Rapid HIV Screen Test from Medmira Laboratories (Canada) (personal communication, Kent Brown, Medical Devices, Health Canada). The cost of an individual Fast-Check HIV-1/2 is approximately $12.50/test (personal communication: Alan Apfeld, BioChem Immunosystems, November 2001). The test kits come in cartons of 30. The Medmira Rapid test comes in cartons of 50 and costs $17/test (personal communication, Maria Patino, Medmira Laboratories). Governments will cover the professional services for HIV testing but not the costs of the rapid test kit. The charge for the laboratory EIA (with labour) varies from laboratory to laboratory. In the United States, overall costs for rapid testing programs appear lower than or comparable with standard testing (14,15).

A number of studies have reported high sensitivity (greater than 99%) and specificity (greater than 98%) for several point-of-care HIV tests (Table 1). Although the results are comparable with standard laboratory tests, one study found that sensitivity for some test kits was as low as 92%, suggesting that not all rapid tests perform optimally (16). It is important to note that studies have been laboratory based or under trial conditions (ie, ideal rather than real life), where strict attention is paid to performing the test properly. Even with laboratory-based HIV testing, the Centers for Disease Control and Prevention (Atlanta, USA) found that EIA-based tests performed below the accuracy levels as advertised by the manufacturers (17). Studies on rapid tests have shown that results may be affected by operator experience and ambient temperatures (18,19). On a positive note, field studies in Honduras and South Africa, using trained personnel, had excellent test performance, with both sensitivity and specificity exceeding 99% (20,21). At this time, it is difficult to know how the test will perform in the real world setting of the busy physician's office or street clinic.

The predictive value of a test refers to the probability of having the disease, given a positive or negative test result. Predictive values relate not only to the test characteristics but also to the prevalence of the disease in the population tested. The predictive values for point-of-care HIV tests have been calculated for several studies (Table 1). A negative test has a high negative predictive value (which explains why it is considered confirmatory). A positive test has a considerably lower positive predictive value. The Centers for Disease Control and Prevention found the positive predictive value to range from 46% at family planning clinics to 88% at drug-treatment centres (22). In the usual testing setting where HIV prevalence is not likely to exceed 1%, two-thirds of positive tests will be false positives. This has been confirmed by Ontario testing results (6).

Rapid tests vary in complexity and configuration. Users need to become familiar with the kit that they are using and must follow the directions carefully (4). Tests are time sensitive and, therefore, need to be timed carefully (4). People with red-green colour impairment may have difficulty reading the colour change. Thought needs to be given to implementing quality control in the clinical setting, so that problems can be detected quickly. Currently, there are no Canadian guidelines describing standards for health care professionals who provide point-of-care HIV testing. However, the health care professional is responsible for care provided. *AIDS Law* (6) has cautioned that health care professionals face potential civil liability if they are not trained and if they negligently administer rapid HIV tests.

Standard HIV tests require venipuncture. Most point-of-care tests require only a finger prick. While it makes inherent sense that patients would prefer a finger prick, this preference was not found to be an important issue in one study (23). In terms of occupational safety, there is much less risk of health care worker exposure with finger prick than with venipuncture (24). The need to return for results has previously been identified as one barrier to acceptance of testing (2,23). It has since been shown that sexually transmitted disease and HIV testing clinic clients preferred the convenience of rapid to standard testing (14).

With rapid testing in a low prevalence setting, most positives will be false positives. The major consequence is psychosocial disruption, which may be significant for some patients. Therefore, with rapid testing, more individuals may experience varying degrees of distress, in some situations requiring psychosocial support. Counsellors at rapid test sites initially expressed concern that a preliminary positive test result would cause the client unnecessary psychological distress (14). With experience, counsellors' concerns resolved and excess stress in those with false positive results was not noted (14). However, studies have not reported on the negative psychosocial impact of false positive results from the client's perspective. Currently, it is unknown if the psychological consequences of a false positive result are outweighed by the relief of a negative rapid test result and the uncertainty of waiting two weeks for a standard result (6).

SUMMARY

The point-of-care tests appear to be very good for screening. When properly performed, point-of-care tests have performance characteristics comparable with standard tests. They have good user and provider acceptability, and safety. A potential advantage could be that, as more infected individuals learn their status and reduce risk behaviours, HIV transmission will decrease (1,2,12). In 1995, 25% of persons testing HIV positive at American publicly funded clinics did not return for their results (22). Kassler et al (14) found a 23% increase in returns for results with rapid testing. There are fewer data on nonreturns in Canada, but the rate appears to be less, 3% to 19%, from an informal poll of several Canadian testing centres (6). A concern expressed about rapid testing is that it will lead to rapid counselling and even to testing without consent (6). At this time, it is difficult to know what the exact role for point-of-care testing in Canada is. Two suggested uses are the screening of women in labour who have not already had HIV testing during pregnancy and the source patients for occupational

exposures. However, one could argue that these are just the situations where informed and voluntary consent cannot be obtained. Also, while it will help in the decision of whether to start postexposure prophylaxis, it will be of limited benefit in the decision of whether to continue. It has also been suggested as an alternative in remote settings. Unfortunately, until timely access to confirmatory testing can be resolved, difficulties persist regarding the implementation of rapid testing in remote areas. Settings where rapid testing may be beneficial include the following: clinics where high risk individuals may be seen and the rate of return for test results is low; drug counselling centres; and sexually transmitted disease and family planning clinics where HIV testing is offered. Currently, standard testing should be employed in Canada, with the exception of certain well defined settings where there are health care professionals trained or experienced in HIV testing and counselling. It is still not clear what these settings are.

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